In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-525V
Filed: March 25, 2025

ROBERTO A. TEJEDA,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Scot Tyler Scheuerman, Scheuerman Law Firm, PLLC, San Antonio, TX, for petitioner.
Benjamin Patrick Warder, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On April 28, 2020, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that he suffered Guillain-Barré Syndrome ("GBS") following receipt of an influenza ("flu") vaccination on December 29, 2017. (ECF No. 1.) For the reasons discussed below, I find that petitioner is *not* entitled to an award of compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury.

In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B). In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In that context, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

As relevant to the allegations of this petition, GBS is a Table injury if onset occurs 3-42 days following receipt of a flu vaccine. 42 C.F.R. § 100.3(a)(XIV)(D). However, respondent observed that petitioner was instead diagnosed by his treating neurologist with chronic inflammatory demyelinating polyneuropathy ("CIDP"), which is not a Table Injury. Moreover, a diagnosis of CIDP is listed among the exclusionary criteria for a Table Injury of GBS. 42 C.F.R. § 100.3(c)(15)(vi). To succeed on a claim that petitioner's flu vaccine caused CIDP, petitioner must satisfy the burden of proof for "causation-in-fact."

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" with the logical sequence being supported by "reputable medical or scientific explanation." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Ultimately, petitioner must satisfy what has come to be known as the *Althen* test, which requires: (1) a medical theory causally connecting the vaccination and the injury; (2) a

logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Id*.

A petitioner may not receive a Vaccine Program award based solely on his or her assertions, but may support the petition with either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. § 300aa-13(b)(1). A petitioner may also rely upon circumstantial evidence. *Althen*, 418 F.3d at 1280. In that regard, the *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. While scientific certainty is not required, that expert's opinion must be based on "sound and reliable" medical or scientific explanation. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359 (Fed. Cir. 2019).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3. Special masters must ensure each party has had a "full and fair opportunity" to develop the record but are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 3(b)(2); Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is required to consider the entirety of the record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines*, 940 F.2d at 1528).

II. Procedural History

Based on the allegations of the petition, this case was initially assigned to the Chief Special Master as part of the Special Processing Unit ("SPU"), a program intended to expedite cases with a high likelihood of informal resolution. (ECF Nos. 7-8.) Petitioner initially filed medical records, affidavits, and a telephone log marked as Exhibits 1-17.

On December 21, 2020, respondent filed his Rule 4(c) Report recommending against compensation. (ECF No. 19.) Whereas the petition alleged petitioner suffered GBS, respondent interpreted the medical records as showing a later diagnosis of CIDP. (*Id*. at 7.) Additionally, respondent contended that onset of petitioner's neurologic condition occurred greater than 42 days post-vaccination. (*Id*.) Accordingly, respondent argued that a Table Injury is not supported in this case. (*Id*.) Respondent also argued that, absent an expert opinion, causation-in-fact could not be supported, but also contended that the timing of onset, which respondent placed at 82 days post-vaccination, would not in any event support a causal inference, especially given that petitioner was otherwise hospitalized around that time for pyelonephritis and sepsis. (*Id*. at 9-11.)

Given petitioner's diagnosis of CIDP and the late onset suggested by the medical records, the Chief Special Master determined that petitioner likely could not establish a Table GBS claim and therefore ordered petitioner to show cause why this case should not be removed from the SPU. (ECF No. 22.) In his order, the Chief Special Master specifically indicated that the case would only remain in SPU if petitioner could explain how his claim could be maintained as a Table claim. (*Id.* at 2.) In response, petitioner filed a memorandum as well as additional affidavits and a medical literature article marked Exhibits 18-23. (ECF Nos. 23-24.) Despite petitioner's argument that onset was earlier than had been assessed by respondent, the Chief Special Master reassigned the case. (ECF Nos. 24-25.) Thus, the case was reassigned to the undersigned in July of 2021. (ECF No. 26.)

Thereafter, a fact hearing was held on December 15, 2021, to assist in addressing the question of onset. (*See* Transcript of Proceedings ("Tr."), at ECF No. 38.) Petitioner and four additional witnesses testified regarding petitioner's condition during the period of alleged onset. (*Id.*) Petitioner also filed an affidavit by his treating physician, Maher Saloum, M.D., who indicated that he has no independent recollection of interacting with petitioner or the events that took place during the period of alleged onset. (Ex. 24.). Following the hearing, I ordered petitioner to file an expert report supporting a cause-in-fact claim under the *Althen* test. (ECF No. 36.) However, I also observed that there was an intersection between the factual question of onset and the other medical questions at issue. (*Id*.) Specifically, I explained that expert opinion was necessary to determine "whether the course of symptoms described by the testimony presented during the hearing is better explained as onset of CIDP or as onset of an infectious illness culminating with petitioner's hospitalization for pyelonephritis and sepsis." (*Id*.) I instructed the parties to have their experts "address the difference between weakness as a constitutional symptom versus weakness as a neurologic sign and whether the available testimony and records are sufficient to make the distinction." (*Id*.)

Petitioner filed expert reports by neurologist Nizar Souayah, M.D., and nephrologist Franco Musio, M.D. (ECF No. 41; Exs. 26-29.[3]) Respondent filed a responsive expert report by neurologist Brian Callaghan, M.D. (ECF No. 44; Ex. A-B.) Petitioner then filed a report by Dr. Souayah responding to Dr. Callaghan's report. (ECF No. 47; Ex. 37.) Thereafter, respondent filed a supplemental report by Dr. Callaghan. (ECF No. 51, Ex. C.) Subsequently, a Rule 5 conference was held on February 15, 2023. (ECF No. 52.) I allowed the parties a further opportunity to have their experts address whether petitioner's earlier symptoms in January and February of 2018 constituted *neurological* or *constitutional* weakness. (*Id.* at 4, 6.) Thereafter, the parties filed a further round of expert reports by Drs. Souayah and Callaghan addressing the preliminary guidance provided in my Rule 5 order. (ECF Nos. 55, 57; Exs. 38, D.) Petitioner then filed a motion for a ruling on the written record, which has been fully briefed. (ECF Nos. 60-63.)

I have concluded that the parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case without an entitlement hearing. S*ee Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs*., 671 F.3d 1368, 1385 (Fed. Cir. 2012)); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

III. Factual Summary

a. As reflected in the medical records

Petitioner's prior medical history does not include any relevant conditions. (*See* Ex. 4.) He received a flu vaccination on December 29, 2017, at age 68. (Ex. 3, pp. 1-2.) He next presented for medical care with his primary care physician, Dr. Saloum, on March 19, 2018. (Ex. 4, pp. 9-10.) However, telephone records indicate that Dr. Saloum's office was contacted by phone on January 29, 2018; January 30, 2018; February 9, 2018; and February 16, 2018. (Ex. 16, pp. 35, 44, 51.) Pharmacy records confirm that Dr. Saloum issued prescriptions to petitioner on dates correlating with these calls. (*See* Ex. 5.) Specifically, Dr. Saloum prescribed petitioner Oseltamivir (*i.e*.

[3] Petitioner's filing initially used alphabetic exhibit designations; however, in a follow up order, I redesignated these exhibits using the next available numeric exhibit designations. (NON-PDF Order, filed on March 31, 2022.)

Tamiflu) on January 29, 2018, montelukast[4] on February 9, 2018, and prednisone[5] and levofloxacin[6] on February 16, 2018. (*Id.* at 3, 6.)

The record of petitioner's March 19, 2018 encounter with Dr. Saloum indicates that petitioner "does have cough and runny nose and discomfort. He had cataract surgery today but cancelled due to his upper respiratory." (Ex. 4, p. 10.) Petitioner also reportedly presented with an infected toe for which he was instructed to continue antibiotics. (*Id.*) However, for reasons discussed below, none of this is accurate. (*See* Findings of Fact, VI(a), *infra*.) Accordingly, this record is not informative as to the reason for petitioner's encounter and Dr. Saloum was unable to provide any additional information. (*See* Ex. 24.) Petitioner was prescribed antibiotics on that date (specifically ciprofloxacin[7] and metronidazole[8]). (Ex. 5, pp. 3, 6.) However, petitioner's subsequent hospital record indicates they were prescribed based on a suspicion of diverticulitis[9]. (Ex. 6a, p. 981.) Although not indicated in the encounter record, a CT scan was apparently performed as petitioner's next encounter was a follow up to review the CT scan results. (Ex. 4, p. 9.)

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[4] Montelukast is an anti-asthmatic drug that binds competitively to leukotriene receptors in the airways, thus inhibiting bronchoconstriction caused by a leukotriene-mediated inflammatory response, that is administered orally. *Montelukast Sodium*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=32122 (last visited Mar. 17, 2025); *Leukotriene Receptor Antagonist*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=56756 (last visited Mar. 17, 2025).

[5] Prednisone is a synthetic glucocorticoid derived from cortisone, administered orally as an anti-inflammatory and immunosuppressant in a wide variety of disorders. *Prednisone*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=40742 (last visited Mar. 17, 2025).

[6] Levofloxacin is "a broad spectrum fluroquinolone antibacterial agent used in the treatment of infection by susceptible organisms, including bronchitis, community-acquired pneumonia, pyelonephritis, urinary tract infections, acute maxillary sinusitis, and skin and soft tissue infections; administered orally, intravenously, and, in the treatment of bacterial conjunctivitis, applied topically to the conjunctiva." *Levofloxacin*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=28157 (last visited Mar. 17, 2025).

[7] Ciprofloxacin is "a fluoroquinolone antibacterial effect against many gram-positive and gram-negative bacteria, including some strains resistant to penicillins, cephalosporins, and aminoglycosides." *Ciprofloxacin*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=9882 (last visited Mar. 17, 2025).

[8] Metronidazole is "an antiprotozoal and antibacterial affective against obligate anaerobes," that is administered orally in the treatment of a T. vaginalis infection in males and intestinal amebiasis; administered orally or intravenously for the treatment of extraintestinal amebiasis and obligate anerobic bacterial infections; and administered intravenously for prophylaxis of colonic perioperative infection. *Metronidazole*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=31073 (last visited Mar. 20, 2025).

[9] Diverticulitis is the inflammation of a diverticulum, especially inflammation related to colonic diverticula, which may undergo perforation with abscess formation. *Diverticulitis*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=14621 (last visited Mar. 17, 2025).

Petitioner returned to Dr. Saloum's office on March 21, 2018 to review his CT scan results. (Ex. 4, p. 9.) The scan showed pyelonephritis. (*Id*.) The record indicates that "patient came very sick to office lethargic, he has fever and his BP was measured as soon as he walked in and it was 60/40, we called 911, and we started him on IV fluids with normal saline." (*Id*.) Petitioner was taken to the hospital by ambulance with presumed septic shock due to his pyelonephritis. (*Id*.) (The testimony discussed separately below also indicates petitioner collapsed while in Dr. Saloum's office.)

Petitioner presented to Mission Trail Baptist Hospital for pyelonephritis and septic shock on March 21, 2018, and was not discharged until April 12, 2018. (Ex. 6a, pp. 981-1301.) The history provided at admission indicated that petitioner "in reality was not having any major medical problems. The patient apparently started feeling sick several days back on Monday[10] when he started with left flank inguinal pain radiated to his back that was evaluated by Dr. Saloum and consider[ed] it was most likely diverticulitis and he was started on antibiotics . . ." (*Id.* at 981.) Later histories during his hospitalization additionally noted that petitioner had suffered the flu about a month prior and that he had been slow to recover from it. (*Id*. at 986, 996.) Upon initial exam, petitioner was definitely in shock and a sepsis protocol was initiated. (*Id*. at 981-82.) Petitioner was "very confused and agitated" during his evaluation, rendering the review of systems presumptively inaccurate. (*Id*. at 982.) However, the intake exam confirmed that petitioner was able to move all four of his extremities. (*Id*. at 983.) Petitioner was admitted to the intensive care unit with diagnoses of septic shock secondary to left pyelonephritis as well as supraventricular tachycardia, lactic acidosis, acute renal failure, coagulopathy, and thrombocytopenia, all believed to be likely related to septic shock. (*Id*. at 983-84.) Chronic conditions of uncontrolled type 2 diabetes and obstructive sleep apnea were also noted. (*Id.* at 984.) However, no concern for any neurologic issue was indicated.

As of March 21, 2018, the day of admission, petitioner's neuromuscular exam showed upper and lower extremity strength of 4/5. (Ex. 6b, p. 482.) As of the next day, upper and lower extremity strength was 3/5. (*Id.*) As of the third day of hospitalization, petitioner had only trace movement with strength of 1/5 in all extremities. (Ex. 6b, pp. 481-82.) Petitioner developed respiratory failure and was thus intubated. (Ex. 6a, p. 994.) After the infectious process had seemingly resolved, petitioner was extubated on April 6, 2018. (*Id*. at 1016.) At that time, it was noted that petitioner "remained very debilitated," and that "[h]e is now battling with the consequences of his acute illness, including delirium caused by ICU and also myopathy with physical deconditioning." (*Id*.) Upon discharge, it was noted that petitioner "had [an] extremely prolonged course," but "[h]is infectious issues resolved. He has been off antibiotics for several days; however, his overall clinical course complicated with severe debility up to the point where the patient hardly can lift an extremity against gravity." (*Id*. at 1000.) Brain imaging was discussed, but the impression was that petitioner's condition "remained nonfocal." (*Id.*) Petitioner was transferred out of the hospital to inpatient rehabilitation on April 12, 2018.

[10] The Monday prior to March 21, 2018, would be March 19, the same date as petitioner's initial encounter with Dr. Saloum.

(*Id.* at 999.) It was noted that he remained confined to his bed and that he had "debility and deconditioned status." (*Id*. at 1004.) Petitioner's neurologic exam the day prior to discharge revealed severe generalized weakness." (*Id*. at 1005.)

Petitioner presented to Warm Springs Rehabilitation Hospital on April 12, 2018, where he remained until June 20, 2018. (Ex. 7, p. 3.) He was evaluated on April 13, 2018, by Dr. Maloy, who noted that petitioner has "ongoing weakness and myopathy of the lower extremities, which is worse from his previous baseline." (*Id*. at 6.) Examination revealed that "[p]atient has ongoing severe lower extremity weakness. He has trace pedal edema. He has 2+ radial and femoral pulses. Cranial nerves II through XII are intact. Patient unable to ambulate secondary to ongoing weakness and ataxia. There is no noted pronator drift . . . ." (*Id*. at 7.) Petitioner was assessed as having "[s]evere weakness with debility secondary to critical illness myopathy," which remained among his discharged diagnoses. (*Id*. at 3, 8.) Petitioner still had deficits at the time of discharged and continued outpatient physical therapy and electrical stimulation was recommended. (*Id*. at 3.)

Subsequently, in December of 2018, petitioner was referred by his rehabilitation physician for an electrodiagnostic consultation to investigate the etiology of his ongoing extremity weakness. (Ex. 8, p. 2.) Petitioner's electrodiagnostic study was abnormal, revealing "evidence of a generalized neuropathic process, axonal in nature, affecting both the motor and sensory nerves," which was noted to be consistent with Acute Motor Sensory Axonal Neuropathy ("AMSAN"). (*Id*. at 5.) It was further remarked that "[c]linically, the patient's symptom presentation, progression, and slight recovery (in a proximal to distal manner) is consistent with this variant of Guillain-Barre syndrome." (*Id*.) However, the history associated with this encounter indicates that petitioner's condition began around the time of his hospital admission in late March and that "[h]e became acutely weak within a period of 3 or 4 days to the extent that he was completely quadriplegic." (*Id.* at 2.)

Petitioner was again admitted to the hospital on January 26, 2019, when he experienced an acute onset of aphasia and slurred speech. (Ex. 14a, pp. 19, 25.) It is indicated within the history of present illness that petitioner had a history of chronic inflammatory demyelinating polyneuropathy ("CIDP"). (*Id.* at 19.) However, the basis for that history is not clear as CIDP is not referenced in any of petitioner's prior medical records. Petitioner remained hospitalized until February 2, 2019, during which time he was treated with IVIg[11] and steroids and reported improvement in his weakness. (*Id*. at 33.) His discharge diagnosis was acute exacerbation of CIDP. (*Id*.)

Petitioner followed up for a neuromuscular evaluation with Nurse Practitioner Valerie Armstrong on February 12, 2019. (Ex. 9, pp. 4-5.) He reported a history of having the flu in mid-January, which was followed by symptoms of aching in the arms and legs and lethargy, followed thereafter by his collapse at his primary care physician's

[11] IVIg is the intravenous administration of immunoglobulin – "any of the structurally related glycoproteins that function as antibodies." *Immunoglobulin*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=24894&searchterm=immunoglobulin.

office at which point, as of March 21, he could no longer stand. (*Id*. at 5.) However, a separate note indicates petitioner "felt fine Prior to Flu shot in Jan 2018." (*Id*. at 6.) The impression was CIDP, with a plan to follow up with a neurologist March. (*Id*. at 9.)

Petitioner saw neurologist Ratna Bhavaraju-Sanka, M.D., on March 18, 2019. (Ex. 9, p. 34.) Dr. Sanka utilized the same history as Nurse Practitioner Armstrong. (*Id*. at 36-37.) However, she further noted that petitioner "is here to follow up his progressive weakness. He reports this started in March 2018 when he was admitted for acute pyelonephritis followed by acute weakness needing intubation and ICU stay." (*Id.* at 42.) Dr. Sanka diagnosed petitioner with an inflammatory neuropathy consistent with CIDP. (*Id*. at 42-43.) Thereafter, petitioner continued to be treated on the basis of his CIDP diagnosis.

Petitioner also filed an affidavit by Dr. Sanka. (Ex. 22.) Dr. Sanka indicated that:

> In February 2019, I became Judge Tejeda's treating neurologist. Judge Tejeda did report that he had no symptoms or problems prior to his flu vaccination. Did he have GBS after the flu vaccination? I cannot say with 100% certainty because the documentation is unclear and lacking. It is possible that he developed GBS as a result of the flu vaccination and it is further possible that at some point that condition progressed to CIDP. But again, the evidence is unclear.

(*Id*. at 2.) However, based on the premise that the course of events prior to petitioner's March 2018 hospitalization is consistent with what petitioner alleges in this case, Dr. Sanka opined that petitioner's condition ("GBS vs. acute onset CIDP") more likely than not was caused by his December 29, 2017 flu vaccination. (*Id*.) Dr. Sanka indicated that "Judge Tejeda's case is complicated by his March 2018 hospital admission for pyelonephritis and sepsis with shock, as he likely experienced an overlapping of symptoms due to possible critical illness neuropathy that he developed during that hospitalization." (*Id.*)

b. As reflected in testimony

i. Petitioner

Petitioner submitted three affidavits in this case (Exs. 1, 17, 21) and also testified during the hearing. (Tr. 102-22). Petitioner testified that prior to vaccination he tried to live a disciplined life and had previously been an athlete when he was younger. (*Id.* at 105.) He did daily calisthenics and walking for exercise, either around his property, on nearby hiking trails, or on a treadmill. (*Id.* at 105-06.) He held a position of Justice of the Peace for Bexar County and had a very high caseload. (*Id.* at 106.) He testified that he continued to work full time until he collapsed at his doctor's office on March 21, 2018. (*Id.* at 113.)

Beginning approximately one week after his flu vaccination, petitioner began experiencing "fatigue, tiredness in my muscles, and also in the arms" as well as a "strange feeling" or "hurting" of his muscles. (Tr. 103; Ex. 17, ¶ 2.) He indicated that, at that time, he didn't "feel anything else, other than a strange feeling of the muscles." (Tr. 103.) At times, petitioner characterized this as "weakness" of the legs, though that was not a part of his initial description during the hearing. (*Id.* at 110, 112; *but see* Ex. 17, ¶ 2 (identifying "gradual weakness of the legs").) Petitioner also testified that he recalled developing numbness and tingling in his legs beginning around middle to late January. (Tr. 109, 113.) Asked whether he experienced weakness in his legs in January of 2018, he initially responded "yes," and added that "I have a general recall that something was going on with my legs." (*Id.* at 106-07.) He indicated that "they were starting to get sore" and then "it progressed for many days." (*Id.* at 107.) He characterized this as culminating his medical office visit of March 21, 2018, at which he collapsed. (*Id.* at 107-08.) He testified that is the last thing he recalls until he awoke from an induced coma. (*Id.* at 108.) He described his collapse as his legs giving out first, followed by blacking out. (*Id.* at 116.) This was the first time that petitioner fell throughout the period from January through March of 2018. (*Id.* at 117.)

However, petitioner testified that he has only "a general and a vague recall about what all happened" in January through March of 2018. (Tr. 104.) For example, although Mrs. Tejeda testified that petitioner had stopped driving during this period, petitioner could not recall that. (*Id.* at 109.) And, although he recalled that he used to walk his property with Gabino Castoreno, as Mr. Castoreno testified, he could not recall when he stopped doing that, though he reasoned it was due to weakness in his legs. (*Id.* at 109-10.) When prompted, petitioner indicated that he was able to recall one time during this period when he could not get up from a seated position without assistance. (*Id.* at 117.) However, his explanation was vague with respect to any specific deficit. Petitioner testified:

> I do recall my wife Lynn asking me, what's wrong. I was on the sofa, and I think I just – I was lying down, and then I sat down when she asked me. And I said – I put my elbows on my knees, and I looked down at the floor, and I said, I don't know. I really thought about that, and I said, I don't know. I'm just still feeling bad, just not me, you know, out of like never feeling the way I used to feel, which is mostly always feeling good, feeling healthy, you know, able to work out, able to go to work, not having any problem.

(*Id.* at 117.) Asked if he had any difficulty standing unassisted, he responded "I think so," before then describing having difficulty getting into his car beginning in mid to late January. (*Id.* at 118.) Petitioner recalled that "I do remember getting weaker and weaker and weaker," but placed this in the context of being "tired and fatigued" and "just wondering, what is going on with my body." (*Id.* at 119.)

With respect to Dr. Saloum's March 19, 2018 medical record, petitioner denied that he was experiencing a runny nose, respiratory issues, or a left toe laceration. (Tr. 108-09, 113-14.) Petitioner testified that he raised his leg weakness with Dr. Saloum at

that encounter, but Dr. Saloum responded that petitioner should wait to see if a previously prescribed antibiotic would help his condition. (*Id.* at 114.) Asked if anything else in his medical records is incorrect, petitioner testified that he has not reviewed his records and does not want to review his records. (*Id.* at 114-15.)

ii. Lynn Tejeda

Lynn Tejeda, petitioner's spouse, submitted an affidavit (Ex. 2) and also testified during the hearing. (Tr. 5-66). In her affidavit, Mrs. Tejeda stated that, about one week following his flu vaccination, petitioner "began complaining to me that he did not feel right. He told me that maybe he was coming down with the flu. He did not have a fever or any stomach symptoms. He said he just didn't feel like his normal self." (Ex. 2, ¶ 3.) During the hearing, she further explained that, while petitioner had been eager to get up and do Saturday morning chores on or about January 6, she found him "laid over" on the couch where he had been putting on his boots. (Tr. 13-15.) She testified that he didn't know what was wrong and stated, "I just feel tired." (*Id.* at 15.) In her testimony, Mrs. Tejeda described petitioner's continuing fatigue from that point forward, describing a reduction in his physical activity, such as daily walks. (*Id.* at 16-17.) She explained that it got to the point that they would come home, and petitioner would immediately lay down on the couch and noted that "[h]e wouldn't come into the family room anymore. He wouldn't watch TV. Just tired." (*Id.* at 17.) In her prior affidavit, Mrs. Tejeda more specifically reported that petitioner had said "he felt weak, especially in the legs." (Ex. 2, ¶ 4.) However, in testimony, she described petitioner as complaining of fatigue and muscle aches. (Tr. 27-28.) She confirmed that petitioner's fatigue is the only symptom she could recall from that period. (*Id.* at 50.)

Mrs. Tejeda first called Dr. Saloum's office about petitioner's condition approximately two weeks after he first appeared sick. (Tr. 20; Ex. 2, ¶ 5.) She confirmed that she reported that petitioner was "very weak and lethargic" and could not recall reporting any other symptom apart from petitioner being "so tired." (Tr. 21, 24.) Dr. Saloum felt petitioner had the flu and prescribed Tamiflu. (*Id.* at 21-22; Ex. 2, ¶¶ 5-6; *see also* Ex. 5, p. 3.) However, petitioner had no fever, no stomach complaints, and no nasal or respiratory congestion. (Tr. 25.) The Tamiflu did not help. (Ex. 2, ¶ 6.) When the Tamiflu did not help, Mrs. Tejeda came to the conclusion that petitioner did not have the flu; however, she acknowledged having no medical basis for this conclusion. (Tr. 59-60.) While she had no idea what condition petitioner was suffering from, she testified that she "knew it was something very different" from the flu. (*Id.* at 60.)

Around this time, Mrs. Tejeda recalled having to help petitioner get up from a sofa; however, she did not know whether this was attributable to fatigue or an inability to get up from the seated position. (Tr. 56-57.) Mrs. Tejeda also indicated that petitioner began using an exercise bike instead of walking on the trails or on a treadmill. (*Id.* at 51-52.) She attributed this to the fact that "his legs just didn't feel right." (*Id.* at 52.) Around the same time, she explained that petitioner stopped driving. (*Id.* at 52-53.) Mrs. Tejeda also recalled that he began taking shorter and slower strides. (*Id.* at 58.)

However, he never fell during this period. (*Id.* at 57.) Mrs. Tejeda did not recall petitioner complaining of numbness. (*Id.* at 58.) She suggested he may have experienced tingling but could not provide any specific recollection. (*Id.* at 58-59.)

Mrs. Tejeda testified that during this period she noticed petitioner was losing muscle mass. (Tr. 29, 32.) She initially attributed this to inactivity, but felt it was not merely a matter of falling out of shape. (*Id.* at 32-33.) In her affidavit, Mrs. Tejeda indicated she called Dr. Saloum's office on February 9, 2018, to refill a routine prescription but took the opportunity to report that petitioner "continued to complain of weakness in his arms and legs. He kept feeling like something was wrong," but was told to give it more time. (Ex. 2, ¶ 7.) In her testimony, she recalled that she called the doctor again on February 16 to report that petitioner was getting "weaker and weaker." (Tr. 30-31.) This time she was told it might be a sinus infection and antibiotics were prescribed. (Ex. 2, ¶ 8.) Petitioner was seen by Dr. Saloum on March 19, 2018. Mrs. Tejeda denied that the encounter was related to an infected toe and further denied that petitioner had a cough or runny nose. (Tr. 39-40.) She noted that petitioner never had a need for cataract surgery. (*Id.* at 39.) Instead, the purpose of the March 19 encounter was "overall fatigue and malaise and lethargy." (*Id.* at 37.) Mrs. Tejeda described the circumstances leading to petitioner's hospitalization for pyelonephritis as beginning on March 21. (*Id.* at 41-45; 61-62.) He was up during the night and experienced onset of abdominal pain[12] early that morning. (*Id.* at 61-62.) Petitioner went into work that morning, but then laid on his couch and said that he could not take the bench and instead wanted to go to the doctor. (*Id.* at 41-44.)

iii. Belinda Cortez

Belinda Cortez submitted an affidavit (Ex. 18) and also testified during the hearing. (Tr. 90-100). Ms. Cortez worked as a lead court clerk under petitioner. (*Id.* at 90-91.) She testified that before receiving his flu vaccination, petitioner was a very energetic person. (*Id.* at 93; Ex. 18, ¶ 4.) Ms. Cortez recalled noticing that petitioner "was not feeling well" during the first week of January and that he did not get better the following week. (Ex. 18, ¶¶ 3-4.) He wasn't "moving around as much as he usually did" and "looked very tired and fatigued." (*Id*. at ¶ 4.) During the hearing, she characterized petitioner as seeming tired and "like he was coming down with a cold." (Tr. 97-98.) When Ms. Cortez initially asked petitioner about how he was feeling, he "downplayed" his condition. (Ex. 18, ¶ 4.) "He just said that he wasn't feeling well. That's basically all he said." (Tr. 94.) However, in her affidavit Ms. Cortez stated that petitioner reported that he was experiencing "weakness in his legs" in mid-January 2018. (Ex. 18, ¶ 5.) When asked to expand on this during the hearing, she responded that petitioner had told her that "he was feeling like his bones hurt," which she associated with the flu. (Tr. 98.) Ms. Cortez went on to explain that she told petitioner it sounded like he still had the flu because with the flu "sometimes our bones hurt and our legs, you know, our body gets weak." (*Id.*) However, as time went on and petitioner continued to not feel well, Ms. Cortez testified that she became doubtful that petitioner had the flu given the duration of his symptoms. (*Id.* at 99*;* Ex. 18, ¶ 5.) She testified that petitioner's

[12] Specifically, back pain that radiated around the side toward the stomach. (Tr. 61.)

condition progressively got worse between early January and his later hospitalization with no period of recovery. (Tr. 95-96.)

iv. Isabell Tejeda

Isabell Tejeda submitted an affidavit (Ex. 20) and also testified during the hearing (Tr. 80-88). Ms. Tejeda is petitioner's sister-in-law by marriage to his brother. (Tr. 80.) Ms. Tejeda recalled that petitioner was "[j]ust tired, weak" during the first weekend in January. (*Id.* at 81.) That weekend, petitioner and his wife were supposed to go to her son's choir performance with the Children's Choir of San Antonio, but they had to cancel. (*Id.* at 81-83.) Ms. Tejeda recalled that there was discussion as to whether petitioner had the flu, but she felt it was unclear because he did not have a temperature or flu symptoms. (Ex. 20, ¶ 2.) After that, she observed him to be "just different, tired, weak." (Tr. 83.) He did not get better, which she would have expected with the flu. (*Id.* at 83-84.) However, when specifically asked if petitioner ever complained of weakness in his legs, she responded "[n]ot specifically to me, no." (*Id.* at 84.) Ms. Tejeda suggested she mostly spoke with Lynn Tejeda about petitioner's health; however, she did not indicate that those conversations discussed leg weakness either. (*Id.*) Ms. Tejeda described reviewing text messages from January of 2018 that she exchanged with Lynn Tejeda but indicated that while the messages discussed petitioner as potentially having the flu, there were no specific mentions of leg weakness. (*Id.* at 85-87.)

v. Gabino Castoreno

Gabino Castoreno submitted an affidavit (Ex. 19) and also testified during the hearing. (Tr. 66-77.) Mr. Castoreno is a general contractor who was hired by petitioner to construct an addition to petitioner's home in the autumn of 2017. (Ex. 19, ¶ 1.) He explained that he and petitioner developed a routine wherein they would talk while petitioner walked the perimeter of his property in the morning. (*Id.* at ¶ 2; *see also* Tr. 68-70.) However, he noticed that this routine changed during the first week of January 2018, at which point petitioner stopped his morning walks. (Ex. 19, ¶ 3; Tr. 70- 71.) Mr. Castoreno recalled that during the week of January 15, 2018, he spoke to Mrs. Tejeda "and I was told that Judge Tejeda was feeling very tired and that his legs were feeling weak, so he didn't feel safe on his feet and wasn't taking his morning walks. She said that he didn't feel right but they didn't know exactly what was wrong with him." (Ex. 19, ¶ 4.) During the hearing, he added that "b]ut, you know, everybody around that time usually has the flu . . . ." (Tr. 71.) He "really thought it was just, you know, a flu that was going around." (*Id.* at 76.) He summarized it as "something was different, you know. He wasn't out and about." (Tr. 71.) He also recalled that "[l]ater in January, I remember seeing Judge Tejeda trying to walk to his car to go to work in the morning and he looked like he was having trouble with his legs." (Ex. 19, ¶ 4.) He noted that, while petitioner typically drove, he wasn't driving at that point and he "just seemed real weak," could "barely walk," and "wasn't himself." (Tr. 71-72.) Asked to describe petitioner's difficulty walking, he described it as "like slow," suggesting it indicated he was weak and couldn't hold himself up. (*Id.* at 76.) He didn't have any further

interaction with petitioner prior to petitioner's hospitalization. (*Id.* at 72.) Mr. Castoreno indicated that the memory of seeing petitioner having troubling walking to his car "sticks in my mind" because he subsequently found out that petitioner was later hospitalized and ultimately unable to move his legs. (Ex. 19, ¶ 5.)

IV. Expert Medical Opinions

a. Petitioner's Nephrology Expert, Franco Musio, M.D.[13]

According to Dr. Musio's assessment of petitioner's history, symptoms of petitioner's pyelonephritis began around March 19, 2018 or after and became clear by the time of his March 21, 2018 follow up at Dr. Saloum's office. (Ex. 28, p. 3.) Manifestations included petitioner's inability to support his own weight, temperature elevation, and left-side flank pain. (*Id*.) Consistent with petitioner's allegations, Dr. Musio separately describes an onset of progressive lower extremity weakness and paresthesia beginning in mid-January of 2018. (*Id.* at 1-2.) He indicates that:

> Detailed review of the above timeline of events clearly shows no intersection nor association between the previously detailed progressive neurologic symptoms beginning in January and the overwhelming systemic (total body) insult of sepsis resulting from the acute infection of the left kidney on March 21, 2018. In fact, pyelonephritis of either a native or transplant kidney very typically presents as a rapid-onset constellation of significant signs and symptoms to include flank/back pain, temperature elevation, fatigue, and lack of well-being, although not commonly with overt sepsis. Notwithstanding Judge Tejeda's increased susceptibility to an infectious process due to his Adult-Onset Diabetes Mellitus (AODM), obesity, and Benign Prostatic Hypertrophy (BPH), there was again no infectious process causing or occurring in tandem with the progressive neurologic decline extending over months from January 2018. Pyelonephritis is not a "smoldering" process that will linger for an extended period of time; rather, the infection and associated symptoms will manifest themselves very rapidly within hours or at most several days after initiation of the infection. Likewise, untreated infection leading to sepsis that lasts for weeks or even months is not survivable. A septic condition rapidly develops and will result in death if it is left undiagnosed and untreated.

[13] Dr. Musio received his medical degree from Georgetown University School of Medicine in 1985. (Ex. 29, p. 1.) He completed his residency in 1986 at Walter Reed Army Medical Center in Washington, D.C. (*Id.*) After completing his internship and active-duty service, Dr. Musio completed his residency in general surgery at Brooke Army Medical Center at Fort Sam in Houston, Texas in 1991. (*Id.*) He then went on to complete a second residency in internal medicine in 1993, also at Brooke Army Medical Center. (*Id.*) In 1995, Dr. Musio completed his fellowship in nephrology at Walter Reed Medical Center. (*Id.*) Since completing his fellowship, Dr. Musio has held various academic appointments, including professorships at the Uniformed Services University of the Health Sciences, Virginia Commonwealth University School of Medicine, and the University of Virginia School of Medicine. (*Id.* at 2.) Currently, he works as a Senior Partner at Nephrology Associates of Norther Virginia. (*Id.* at 3.) He is board certified in internal medicine and nephrology and maintains his medical license in Virginia. (*Id.* at 2.) Dr. Musio has authored a handful of articles and abstracts on various nephrology topics. (*Id.* at 9-10.)

(*Id.* at 3.)

Dr. Musio acknowledged that respiratory and gastrointestinal infections can trigger inflammatory neuropathy; however, "Judge Tejeda's inflammatory neuropathy signs and symptoms preceded the onset of his illness with pyelonephritis and thus the acute kidney infection could not have been the triggering catalyst for the inflammatory neuropathy." (Ex. 28, p. 5.) Dr. Musio also added that he was unable to find any literature indicating that a kidney infection is a recognized trigger for inflammatory neuropathy. (*Id*.)

b. Petitioner's Neurology Expert, Nizar Souayah, M.D.[14]

Dr. Souayah explained that CIDP represents a group of acquired polyneuropathies that are characterized clinically by symmetric weakness affecting the proximal and distal muscles and progressing over the course of at least two months. (Ex. 26, p. 12.) It has an estimated prevalence of 8.9 per 100,000 with a higher prevalence among men than women. (*Id.* (citing R.S. Laughlin, et al., *Incidence & Prevalence of CIDP & the Association of Diabetes Mellitus*, 73 NEUROLOGY 39 (2009)).) It can be either progressive or relapsing-remitting and has a variable prognosis. (*Id*.) According to one study, more than 90% of CIDP patients initially improve with immunosuppressive therapy. (*Id*. (citing Richard J. Barohn, M.D. et al., *Chronic Inflammatory Demyelinating Polyradiculoneuropathy: Clinical Characteristics, Course, and Recommendations for Diagnostic Criteria*, 46 ARCHIVES OF NEUROLOGY 878 (1989)).)[15]

[14] Dr. Souayah received his medical degree in 1990 from the Medical School of Tunis in Tunisia. (Ex. 27, p. 1.) In 1997, he completed an internship in internal medicine at the University of Pennsylvania Health System, Presbyterian Medical Center in Philadelphia. (*Id.*) He then went on to complete his residency in neurology at Temple University Hospital in Philadelphia in 2002. (*Id.*) Additionally, Dr. Souayah completed a fellowship in electromyographic and neuromuscular disease at Harvard Medical School in 2003 and had a postdoctoral appointment at Drexel Medical School from 2003 to 2004. (*Id.* at 1-2.) Since completing his postdoctoral training, Dr. Souyah has held various academic appointments at Rutgers University in New Jersey. (*Id.* at 2.) Currently, Dr. Souyah serves as a professor of neurology, physiology, pharmacology, and neurosciences at Rutgers University Department of Neurology and Rutgers-New Jersey Medical School. (Ex. 26, p. 1.) He also holds clinical appointments as a neurologist at several hospitals in New Jersey and is currently the MDA Clinic Director. (Ex. 27, pp. 2-3, 20.) In his clinical practice, Dr. Souayah regularly diagnoses and treats patients with neurological conditions including inflammatory neuropathies. (Ex. 26, p. 7.) He is board certified in neurology, with a subspeciality in electrodiagnostic medicine and neuromuscular disorders, and he maintains his medical license in New Jersey. (*Id.* at 1.) Dr. Souayah has authored several peer-reviewed journal articles, book chapters, and abstracts that he contends inform the issues of this case. (*Id.* at 1-7; *see also* Ex. 27, pp. 22-43.)

[15] Except where otherwise filed by respondent, the medical literature cited by Dr. Souayah has not been filed into the record of this case. For purposes of this decision, given that the analysis that follows turns on the threshold question of my resolution of the parties' factual dispute as to symptom onset, I simply presume that Dr. Souayah's statements are supported by their accompanying citation. However, had this threshold issue not resolved the case, then it would be necessary to have petitioner file the cited literature.

Dr. Souayah opined that both vaccination and infection are known triggers of CIDP. (Ex. 26, p. 14.) He cited a study by McCombe, et al., that found that 32% of a group of 92 CIDP patents had a history of either vaccination or infection (respiratory or gastrointestinal) within the six weeks prior to onset of neurologic symptoms. (*Id*. (citing P.A. McCombe et al., *Chronic Inflammatory Demyelinating Polyradiculoneuropathy: A Clinical and Electrophysiological Study of 92 Cases*, 110 BRAIN 1617 (1987)).) In a case series reported by Gérard Said, 9 out of 100 CIDP patients had a preceding "non-specific flu like syndrome." (*Id*. (citing Gérald Said, *Chronic Inflammatory Demyelinating Polyneuropathy*, 16 NEUROMUSCULAR DISORDERS 293 (2006)).) Dr. Souayah proposed that CIDP results from a combination of antibody and cellular immunity dysregulation leading to destruction of the myelin sheath and secondary axonal loss. (*Id*. at 14-15.) He opined that antigenic material within the flu vaccine can be sufficiently similar to components of myelin tissue to result in molecular mimicry and cross-reaction, causing antibodies produced in response to the vaccine to attack the myelin. (*Id*. at 22.) He asserted that the same mechanism could explain how the flu vaccine can cause GBS. (*Id*. at 34.)

Dr. Souayah based his opinion on his understanding that "[a]bout one week after the influenza vaccination, Judge Tejeda began to develop general fatigue and a gradual weakness in his legs. Throughout January of 2018, the fatigue and weakness progressed." (Ex. 26, p. 8.) Dr. Souayah placed onset of numbness on February 16, 2018. (*Id*.) He stressed that petitioner's neuromuscular exam on March 21, 2018, the day of his hospital admission, recorded reduced muscle strength of 4/5 in all extremities. (*Id.* at 9.) He further explained that the following day's exam showed reduced strength of 3/5 in all extremities and that, by March 23, 2018, petitioner was quadriplegic with muscle strength of 1/5 in all extremities. (*Id*. (citing Ex. 6b, pp. 481-82).) Thus, Dr. Souayah opined that petitioner's clinical course began with lower extremity weakness beginning in the first week of January, later progressing to his upper extremities, with onset of numbness and loss of deep tendon reflexes occurring 10 weeks after initial symptom onset and 11 weeks post-vaccination. (*Id*. at 13.)

Although a monophasic course would normally be more consistent with GBS, the length of time over which symptoms progressed (greater than eight weeks) is more consistent with CIDP. (Ex. 26, p. 13.) Petitioner's response to IVIg treatment also supports a CIDP diagnosis. (*Id.*) Finally, Dr. Souayah agreed that petitioner's later electrodiagnostic study confirmed that petitioner suffered a severe sensorimotor polyneuropathy rather than a myopathy but disagreed that the study revealed whether the condition had a primary demyelinating or axonal etiology. (*Id*. at 14.) Thus, Dr. Souayah opined that petitioner suffered CIDP. (*Id.* at 13-14.) He cautioned, however, that "[w]ithout confirmatory testing performed at the time of hospitalization ([c]erebrospinal analysis, [e]lectrodiagnostic testing and muscle & nerve biopsy), I base his diagnosis on the history and clinical progression as well as on the neuromuscular evaluation and electrodiagnostic testing performed on December 18, 2018." (*Id*. at 13.)

Dr. Souayah opined that critical illness myopathy cannot explain petitioner's condition because (1) muscle strength was 4/5 upon hospital admission and

development of quadriplegia over two days "is not enough time to attribute the weakness to critical illness myopathy," (2) absence of deep tendon reflexes is not compatible with new onset of myopathy, and (3) there is no muscle biopsy to support myopathy. (Ex. 26, p. 13.) Dr. Souayah acknowledged that critical illness myopathy can be associated with prolonged ICU stays, but stressed in his second report that petitioner's decline of motor strength took place over the course of only 36 hours and occurred prior to his intubation, with all relevant symptoms manifesting within 48 hours of admission. (Ex. 37, p. 2.)

Dr. Souayah ultimately concluded:

> It is entirely plausible that there was more than one disease process causing Judge Tejeda's condition and that signs and symptoms of those processes overlapped. It is improbable, if not impossible, that infection and [critical illness myopathy/critical illness polyneuropathy] were the only causes of the patient's illness because significant symptoms of his condition occurred prior to the March 2018 kidney infection and resulting hospitalization. Instead, it is probable that while the patient did suffer from infection and sepsis, his condition was initiated by an influenza vaccine causing an inflammatory neuropathy, either GBS or CIDP, with demyelination and secondary severe axonal loss.

(Ex. 37, p. 3.)

In his final report, Dr. Souayah addressed the distinction between constitutional and neurologic weakness as prompted by my Rule 5 Order. (Ex. 38.) Dr. Souayah opined that petitioner's symptoms in January and February of 2018 most likely constituted neurologic weakness because (1) they cannot be explained by his pyelonephritis and sepsis, (2) there is no alternative explanation available, (3) he has assessed the symptoms as progressive beginning in the legs, and (4) the symptoms were not systemic. (*Id.* at 1-2.)

c. Respondent's Neurology Expert, Brian Callaghan, M.D.[16]

Dr. Callaghan opined that petitioner's most likely diagnosis is critical illness polyneuropathy and myopathy. (Ex. A, p. 5.) He opined that petitioner's history, physical examination, and EMG/NCS support this diagnosis and further stressed that this was the diagnosis of the treating physicians during his hospitalization and rehabilitation. (*Id*.) Based on his review of the record, Dr. Callaghan concluded that petitioner suffered an influenza infection accompanied by symptoms of muscle pain, lethargy, and headaches, sometime in January or February of 2018. (*Id*.) Thereafter, in mid-to-late March he experienced a course of fevers and flank pain ultimately diagnosed as pyelonephritis and septic shock. (*Id*.) Myopathy was first noted during his March 2018 hospitalization, during which he was intubated and had a prolonged stay in the ICU. (*Id.*) A later EMG/NCS conducted in December of 2018 subsequently confirmed a motor and sensory axonal neuropathy. (*Id*.) Dr. Callaghan agreed that petitioner's pyelonephritis would not explain symptoms in January or February, but opined that petitioner's earlier symptoms, which were "quite non-specific," were consistent with the flu, as had been diagnosed, or other viral infections. (Ex. C, p. 1.) He stressed that none of the symptoms were indicative of CIDP. (*Id*.) Dr. Callaghan opined that petitioner's earlier symptoms of fatigue and lethargy are consistent with constitutional weakness and there is no evidence that petitioner had any neurologic symptoms prior to his critical illness caused by pyelonephritis. (*Id*. at 2.)

According to Dr. Callaghan, the diagnostic criteria for critical illness polyneuropathy requires the following: (1) the patient is critically ill; (2) non-neuromuscular causes for weakness and difficulty weaning from ventilation are excluded; (3) EMG/NCS reveals evidence of axonal sensory and motor polyneuropathy; and (4) there is no decremental response on repetitive nerve stimulation. (Ex. A, p. 5 (citing Nicola Latronico & Charles F. Bolton, *Critical Illness Polyneuropathy & Myopathy: A Major Cause of Muscle Weakness & Paralysis*, 10 LANCET NEUROLOGY 931 (2011) (Ex. A, Tab 1)).) Consistent with these criteria, Dr. Callaghan observed that petitioner was critically ill from pyelonephritis and sepsis, requiring intubation and a long ICU stay,

[16] Dr. Callaghan received his medical degree from the University of Pennsylvania Medical Center in 2004. (Ex. B, p. 1.) He also earned a master's degree in clinical research design and statistical analysis from the University of Michigan. (*Id.*) Dr. Callaghan completed his internship in 2005 and his neurology residency in 2008 at the University of Pennsylvania Medical Center in Philadelphia. (*Id.*) He then went on to complete a neuromuscular fellowship at the University of Michigan Health System in Ann Arbor in 2009. (*Id.*) Additionally, Dr. Callaghan completed a health policy fellowship at the University of Michigan's Center for Healthcare Research and Transformation in 2016. (*Id.*) Since completing his neuromuscular fellowship, Dr. Callaghan has held numerous academic appointments, with professorships in neurology at the University of Michigan Health System, the University of Michigan Medical School, and the VA Ann Arbor Healthcare system. (*Id.*) Currently, Dr. Callaghan serves as an associate professor of neurology at the University of Michigan Health System and the University of Michigan Medical School. (*Id.*) He also currently serves as a staff physician for the VA Ann Arbor Health System's Department of Neurology. (*Id.* at 2.) Additionally, Dr. Callaghan currently holds an administrative appointment as the Co-Director of the Neuromuscular Division at the University of Michigan Health System. (*Id.*) He is board certified in neurology and maintains his medical license in Michigan. (*Id.* at 1.) He has published over 100 peer-reviewed articles on various neurological topics including neuropathy. (*Id.* at 14-21.)

remained weak after non-neurologic issues improved, had EMG/NCS confirmation of axonal sensory and motor neuropathy, and that there was no documented decremental response. (*Id*.) Contrary to the points raised by Dr. Souayah, Dr. Callaghan indicated that reduced reflexes are seen in both critical illness myopathy and polyneuropathy and that electrophysiologic changes resulting from critical illness polyneuropathy can occur quite rapidly and in as little as hours. (*Id*. at 6 (citing Latronico & Bolton, *supra*, at Ex. A, Tab 1).) Dr. Callaghan opined that petitioner's rapid decline in the ICU "is exactly in keeping with critical illness myopathy and neuropathy." (Ex. C, p. 1.) According to Dr. Callaghan, muscle biopsy is not a part of the diagnostic criteria for polyneuropathy. (Ex. A, p. 6.)

Dr. Callaghan disagreed that petitioner met the diagnostic criteria for CIDP, because he did not have evidence of demyelinating features on NCS. (Ex. A, p. 6.) Nor does petitioner's treatment with IVIg support the diagnosis. (*Id.*) Despite having been treated with IVIg for a year, petitioner saw no improvement in his neurologic exams over that period. (*Id*.) Even if one concluded that petitioner did have CIDP, one of his two infections (influenza or pyelonephritis) would be a more likely cause. (*Id*. at 7.)

Dr. Callaghan concluded that:

> Overall, the Petitioner's medical history, examination, and testing, including EMG/NCS testing, are consistent with a diagnosis of critical illness polyneuropathy and myopathy. Even if the petitioner did have CIDP, the current evidence does not support a causal association between influenza vaccination and CIDP. Moreover, a non-vaccine cause, infections, would be more likely to lead to CIDP than vaccination. There is also insufficient evidence of a biologic mechanism linking influenza vaccination to either critical illness polyneuropathy or CIDP. Finally, GBS and CIDP are distinct conditions; therefore, evidence pertaining to GBS does not necessarily pertain to CIDP.

(Ex. A, p. 8.)

In his final report, Dr. Callaghan responded to Dr. Souayah's assessment of constitutional versus neurologic weakness. (Ex. D.) Dr. Callaghan disagreed that the record supports the presence of progressive leg weakness as identified by Dr. Souayah. (Ex. D, p. 1.) He also stressed that the mere progression of weakness is not informative, given that constitutional weakness can worsen depending on the course of the underlying illness. (*Id*.) Dr. Callaghan disagreed that the weakness is otherwise unexplained given that petitioner was contemporaneously diagnosed with the flu. (*Id.*) And, while he agreed that petitioner's pyelonephritis itself would not explain petitioner's earlier symptoms, he noted that pyelonephritis is typically sequela to other infections, such as urinary tract infections. (*Id.*) Moreover, if petitioner's reported weakness were neurologic, consistent with CIDP, the additional presence of numbness and tingling would be expected. (*Id*.)

V. Party Contentions

Although petitioner acknowledges that he ultimately received a diagnosis of CIDP from some of his physicians, he notes that he carried an initial diagnosis of GBS and that none of his medical records contradict that diagnosis given that GBS can later develop into CIDP. (ECF No. 60, p. 7.) In either event, he argues that Dr. Souayah has presented a theory of causation by which the flu vaccine may cause either GBS or CIDP. (*Id*. at 7-9.) He asserts that the medical records coupled with his experts' opinions support a logical sequence of cause and effect implicating the flu vaccination as the cause of his condition. (*Id*. at 9-16.) Petitioner disputes that his neurologic condition could be the result of a critical illness myopathy related to his pyelonephritis and sepsis. (*Id*.) Moreover, even if petitioner did develop critical illness myopathy during his later hospitalization, this could merely be superimposed over an earlier developing CIDP.[17] (ECF No. 63, p. 4.) Petitioner asserts that his condition began one-week post-vaccination with onset of fatigue and general weakness ascending from the legs with numbness and tingling developing in mid-January of 2018. (ECF No. 60, pp. 1-2, 17-18.) However, he acknowledges that his expert, Dr. Souayah, placed onset of extremity weakness with absent reflexes at about 10-11 weeks following these alleged initial symptoms. (*Id*. at 17-18.) Petitioner argues that a one-week post-vaccination onset supports a causal inference, but does not explicitly identify an outer limit for a temporal association. (*Id*. at 18.) Petitioner argues that the hearing testimony in this case should be viewed as more persuasive than the medical records, particularly those of Dr. Saloum, because the medical records are incomplete, inconsistent, and/or inaccurate. (*Id.* at 18-19; *see also* ECF No. 63, pp. 2-4.)

Respondent acknowledges that petitioner's pyelonephritis would not explain his symptoms occurring in January and February of 2018; however, respondent disputes that there is preponderant evidence supporting the presence of either progressive leg weakness or numbness and tingling during January and February of 2018. (ECF No. 61, pp. 14-15, n.7.) Respondent asserts that petitioner's January and February symptoms were non-specific, mainly consisting of lethargy, headaches, and muscle pains, and are consistent with his flu diagnosis around that time. (*Id*. at 18.) Respondent asserts based on his expert's opinion that petitioner did not suffer either GBS or CIDP, but instead suffered critical illness myopathy that developed during his later hospitalization while he was critically ill from pyelonephritis and sepsis. (*Id.* at 15.) Although respondent acknowledges that petitioner was later diagnosed with CIDP, he contends that petitioner did not actually fit the diagnostic criteria for CIDP. (*Id*. at 17-18.) Furthermore, respondent argues that petitioner cannot meet the *Althen* test with respect to petitioner's alleged CIDP, stressing that CIDP cannot be equated to GBS, and that onset would not support an inference of causation. (*Id.* at 19-35.)

[17] Petitioner cites *Shyface*, 165 F.3d at 1344, for the proposition that he can prevail even if his ultimate condition was the result of vaccine-caused CIDP and critical illness myopathy acting concurrently. (ECF No. 63, p. 7.)

VI. Discussion

a. Findings of Fact

Pursuant to the Vaccine Act, a petitioner must prove the facts underlying their claim by a preponderance of the evidence. § 300aa-13(a)(1)(A). A special master must consider the record as a whole and is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 300aa-13(b)(1). However, the Federal Circuit has held that contemporaneous medical records are ordinarily to be given significant weight due to the fact that "[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras*, 993 F.2d at 1528.

Yet, this precept is not absolute. *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (stating that "[w]e reject as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions"). Medical records are afforded substantial weight when they are clear, consistent, and complete. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *1, 19-20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Afterall, "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs*., No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). Importantly, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992).

When witness testimony is offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the special master must consider the credibility of the individual offering the testimony. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). Notably, although special masters are not bound by the rules of evidence and instead consider all relevant and reliable evidence as required under Vaccine Rule 8(b), "lay opinions as to causation or medical diagnosis may be properly characterized as 'subjective belief' when the witness is not competent to testify on those subjects." *James-Cornelius v. Sec'y of Health & Human Servs*., 984 F.3d 1374, 1380 (Fed. Cir. 2021) (applying Rule 701 of the Federal Rules of Evidence in the Vaccine Program).

In determining whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, there must be evidence that this decision was the result of a rational determination. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 416-17 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence" contained in the record. *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 300aa-12(d)(3); Vaccine Rule 8), *aff'd sub nom. La Londe v. Sec'y of Health & Human Servs.*, 746 F.3d 1334 (Fed. Cir. 2014); *see also id.* at 417.

Following this guidance, considering the record as a whole, and applying a preponderant burden of proof to petitioner's allegations, I find the following:

- The fact witness testimony provided by all five witnesses was credible in the sense of seeking to present an honest recollection of events. However, this does not mean the testimony was reliable or persuasive in all respects. In particular, although not completely discounted, petitioner's own affidavits and testimony cannot be fully credited in light of his testimony that his critical illness has caused ongoing memory problems, he does not wish to familiarize himself with his prior medical records, and that he largely only has "general" or "vague" recall of the events of January through March of 2018. (Tr. 104-05; 120-21.)

- Petitioner experienced a change in his health beginning on or about January 6, 2018. (Tr. 12-15.) Petitioner's primary complaints prior to March of 2018 were generalized weakness, fatigue, and lethargy. (*Id.* at 16-17, 21, 27-28, 37, 50; 103.)

- Petitioner's symptoms of generalized weakness, fatigue, and lethargy, that began on or about January 6, 2018, were diagnosed as the flu by telephone encounter. Mrs. Tejeda called petitioner's primary care doctor on January 29, 2018, and reported that petitioner was experiencing fatigue and that she suspected the flu. (Tr. 20-21, 24.) He was prescribed Tamiflu the same day. (*Id.* at 24; Ex. 5, pp. 3, 6.) Other witnesses were also under the impression petitioner had been diagnosed with the flu.

- Petitioner's flu diagnosis was never revisited or retracted. Mrs. Tejeda testified that petitioner discontinued Tamiflu and that she developed a subjective lay belief around that time that petitioner's condition was not explained by the flu.[18] (Tr. 59-60.) However, she acknowledged she had no medical basis for this belief (*Id*.), and there is no record available to indicate any physician so opined. Other lay witnesses likewise indicate that they came to doubt the flu diagnosis. However, the medical records reflect that Mrs. Tejeda and petitioner continued to

[18] Petitioner and Mrs. Tejeda provided conflicting testimony regarding whether he experienced strange dreams as a side effect of the Tamiflu that might explain his discontinuance of the treatment. (Tr. 22, 60, 110-11.)

report to treating physicians that petitioner had suffered the flu even after petitioner's later hospitalization. (Ex. 6a, pp. 986, 996; Ex. 9, p. 5.)

- Petitioner testified that he experienced progressive weakness in his legs during January and February of 2018. (Tr. 107-08.) However, this is not preponderantly supported for the following reasons:

    - Progressive leg weakness occurring throughout January and February is not reflected in any contemporaneous medical record, or in any history within petitioner's initial treatment records during his March 2018 hospitalization. Moreover, there is no contemporaneous medical record available that includes a physical examination or neurologic evaluation inclusive of possible extremity weakness prior to March 21, 2018.

    - Petitioner was inconsistent in his own testimony in describing his symptom as either "weakness" or muscle aches and, as noted above, his memory of this period is limited. (Tr. 103, 104, 106-07, 110, 112.) Therefore, based on petitioner's testimony, progressive leg weakness cannot be distinguished from petitioner's flu or flu-like presentation, which included generalized weakness, beginning around January 6. Medical records as late as February of *2019*, indicate that petitioner was reporting his extremity symptoms of January and February of 2018 as being "flu like muscular pain" and lethargy. (Ex. 9, p. 5.)

    - Leg weakness is, at best, inferentially suggested in the testimony of other witnesses and these accounts do not clearly distinguish petitioner's symptoms as leg weakness as opposed to manifestations of the otherwise preponderantly supported symptoms of flu-like lethargy and generalized weakness. Both petitioner and Mrs. Tejeda testified that petitioner at some point in late January required assistance on one occasion rising off his sofa. (Tr. 56-57, 117.) However, neither could not attribute this to any specific deficit rather than simply being fatigue. (*Id*.) Additionally, Mrs. Tejeda testified that at some point during this period petitioner began to feel steadier on an exercise bike than on a treadmill. (*Id.* at 51-52.) Mrs. Tejeda subjectively feared petitioner would fall; however, he did not fall during this period. (*Id.* at 41-42.) Mrs. Tejeda testified that petitioner's gait changed, with him taking shorter and slower steps. (*Id.* at 58.) Mr. Castoreno also specifically observed petitioner walking with difficulty. (*Id.* at 71-72.) However, there is no evidence to indicate that petitioner became unable to walk prior to the day of his hospitalization or ever utilized a cane or other assistance device.

- Petitioner testified that in the months prior to his hospitalization he experienced numbness and tingling in his legs (Tr. 109); however, this is not preponderantly established given the reduced weight afforded petitioner's testimony as noted above. The presence of numbness and tingling in the legs is not specifically supported by any contemporaneous medical record or by other witness testimony, apart from one unsubstantiated reference to tingling by Mrs. Tejeda. (*Id.* at 58-59.)

- Petitioner began experiencing fevers around mid-March, about 8 days prior to his March 21 hospitalization. (Ex. 6a, p. 986.) He began experiencing left flank pain sometime between March 18 and March 21. (*Id.* at 981; Tr. 61-62.) This likely represents onset of petitioner's pyelonephritis as Dr. Musio opined. (Ex. 28, p. 3.)

- Petitioner presented to Dr. Saloum on March 19, 2018; however, it is unlikely that the medical record at Exhibit 4, pp. 9-10, purporting to be a record of petitioner's March 19, 2018 appointment with Dr. Saloum, accurately reflects petitioner's encounter. There are several discrepancies that the witnesses are persuasive in characterizing as errors.[19] Thus, there is not preponderant evidence supporting the presence of congestion and runny nose or the description of physical examination contained in this record.

- Petitioner's March 2018 hospitalization records are consistent with a rapid onset of neurologic extremity weakness occurring at that time. Petitioner was able to move all four limbs at the time of his critical care assessment and his subsequent neuromuscular evaluations reflect a rapid decrease in extremity strength following admission. (Ex. 6a, p. 983, Ex. 6b, pp. 481-82.) His discharge summary also indicates that the hospital course was complicated by the development of debility, which further suggests this process occurred during hospitalization. (Ex. 6a, p. 1000.) By the time of discharge, petitioner had severe generalized non-focal neurologic weakness. (*Id*.) Dr. Souayah identified petitioner's loss of reflexes as occurring 10 weeks after the onset of petitioner's January 6 illness, which coincides with his critical illness. (Ex. 26, p. 13.)

[19] First, the record indicates petitioner had cancelled a surgery to treat cataracts due to upper respiratory concerns evidenced by a runny nose and congestion. (Ex. 4, p. 10.) However, there is no other evidence of record to suggest that petitioner had cataracts or ever scheduled a surgery to treat that condition. Second, both petitioner and Mrs. Tejeda testified that petitioner did not have an infected laceration on his toe as indicated in the medical record. (Tr. 39-40, 108-09.) Third, petitioner's subsequent hospitalization records indicate that Dr. Saloum's impression was diverticulitis, which is not reflected in this medical record. (*See* Ex. 4, pp. 9-10; Ex. 6a, pp. 981 ,993.)

b. *Althen* Analysis

Even assuming *arguendo* that CIDP can be caused by the flu vaccine for purposes of *Althen* prong one, petitioner cannot meet his burden of proof under either *Althen* prong two or *three* in light of the above findings of fact.

The second *Althen* prong requires proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant,* 956 F.2d at 1148. However, petitioner may support his claim by presenting either medical records or the opinion of a competent medical expert. § 300aa-13(a)(1). Medical records and/or statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

In this case, based on the facts as I have found them, Dr. Callaghan is persuasive in opining on respondent's behalf that petitioner did not likely experience *neurologic* weakness prior to his critical illness. Although petitioner clearly suffered an illness of some kind in January, the evidence preponderates in favor of the finding that petitioner's symptoms prior to his March 21, 2018 hospitalization constitute constitutional symptoms of fatigue, lethargy, and generalized weakness, with no preponderantly supported indication of progressive leg weakness or numbness and tingling that could be indicative of an inflammatory neuropathy such as CIDP. This undercuts the opinions of Drs. Musio, Souayah, and Sanka, in two ways.

First, all three physicians (Drs. Souayah, Sanka, and Musio) based their diagnostic assessments in part on the fact that petitioner was experiencing neurologic symptoms consistent with an inflammatory polyneuropathy prior to onset of his pyelonephritis and critical illness (Ex. 22, p. 2; Ex. 26, pp. 8, 13; Ex. 28, pp. 1-2, 5), whereas I have found petitioner's onset of neurologic symptoms first occurred during petitioner's hospitalization, which is more consistent with Dr. Callaghan's assessment of a critical illness myopathy/polyneuropathy (Ex. A, p. 5). Although Dr. Souayah opined that petitioner's rapid decline is too fast to be due to a critical illness myopathy/polyneuropathy (Ex. 26, p. 13; Ex. 37, p. 2), Dr. Callaghan has rebutted that opinion. (Ex. A, p. 6 (citing Latronico & Bolton, *supra*, at Ex. A, Tab 1).)

Dr. Souayah further opined that critical illness myopathy cannot explain petitioner's condition, because he experienced onset of neuromuscular weakness early in the course of his hospitalization and prior to being exposed to precipitating factors such as a prolonged ICU stay and intubation. (Ex. 38, p. 3.) However, regardless of

whether prolonged hospitalization and/or intubation are additionally implicated, sepsis is in itself a risk factor for critical illness polyneuropathy. (Latronico & Bolton, *supra*, at Ex. A, Tab 1, p. 4.) Dr. Souayah otherwise explained that:

> Once the bacteria entered Judge Tejeda's bloodstream, it traversed his entire body and the disease process reached the point of sepsis . . . The longer sepsis is left untreated, the more likely the patient's condition will deteriorate even when antibiotics are started and administered. In Judge Tejeda's case, his rapid deterioration was more likely due to a systemic inflammatory cascade activated by the release of bacteria and their toxins. This is often referred to as septic shock and indeed that was in part the diagnosis that his treating physicians reached.

(Ex. 38, p. 3.) In that regard, petitioner was specifically noted to already have been in septic shock upon admission to the hospital. (Ex. 6a, pp. 981-84.)

Moreover, critical illness myopathy was the diagnosis of the treating physicians who initially treated petitioner during his critical illness and inpatient rehabilitation. (Ex. 6a, p. 1016; Ex. 7, pp. 3, 8.) Absent evidence of neurologic symptoms predating petitioner's critical illness, there is no readily apparent reason to discard petitioner's initial critical illness myopathy/polyneuropathy diagnosis in favor of CIDP. Dr. Callaghan explained that petitioner's subsequent electrodiagnostic study, which appears to have been what prompted a reassessment of petitioner's diagnosis, is consistent with critical illness polyneuropathy. (Ex. A, p. 5.) Although Dr. Musio is persuasive in opining that petitioner's earlier symptoms are not explained by his pyelonephritis, this does not call into question the relationship between petitioner's pyelonephritis and his *later* manifesting neurologic symptoms.

Second, Drs. Souayah's and Sanka's causal assessment vis-à-vis the preceding flu vaccination was likewise predicated on the same assumption that petitioner experienced onset of symptoms of inflammatory polyneuropathy during the first week of January, within one week of the prior December 29, 2017 vaccination. (Ex. 22, p. 2; Ex. 26, pp. 8, 13; Ex. 28, pp. 1-2, 5.) Dr. Souayah explained that a causal inference is supported when an infection or vaccination has occurred within the six weeks preceding onset of CIDP. (Ex. 26, p. 14.) Yet, there is not preponderant evidence of neurologic symptoms arising in the six weeks following petitioner's vaccination for the reasons discussed above. Moreover, as Dr. Callaghan pointed out, the evidence does otherwise support the conclusion that petitioner suffered an apparent illness of some kind beginning in January of 2018, and both Drs. Souayah and Callaghan agree that CIDP is often post-infectious. (Ex. 26, p. 14; Ex. A, p. 7.) Without the close temporal relationship between vaccination and onset of neurologic complaints assumed by Drs. Souayah and Sanka, there is little reason to pinpoint petitioner's vaccination as the most likely cause of his alleged CIDP.

Ultimately, the literature submitted by Dr. Callaghan emphasizes the fact that patient history is "the most important differential criterion" in distinguishing critical illness

polyneuropathy from GBS. (Latronico & Bolton, *supra*, at Ex. A, Tab 1, p. 7.) And Dr. Souayah likewise confirmed in his report that, given the lack of contemporaneous diagnostic testing, he based his diagnosis "on the history and clinical progression." (Ex. 26, p. 13.) Therefore, because Drs. Souayah, Sanka, and Musio, based their opinions on a factual assumption regarding that history that is not preponderantly supported on this record, their opinions are not credited. *Burns*, 3 F.3d at 417 (holding that "[t]he special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner's medical expert."); *see also Rickett v. Sec'y of Health & Human Servs.,* 468 Fed. Appx. 952, 958 (Fed. Cir. 2011) (holding that "it was not error for the Special Master to assign less weight to Dr. Bellanti's conclusion regarding challenge-rechallenge to the extent it hinged upon Mr. Rickett's testimony that was inconsistent with the medical records"); *Dobrydnev v. Sec'y of Health & Human Servs.,* 566 Fed. Appx. 976, 982-83 (Fed. Cir. 2014) (holding that the special master was correct in noting that "when an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp*., 509 U.S. 209, 242 (1993)); *Bushnell v. Sec'y of Health & Human Servs.,* No. 02-1648V, 2015 WL 4099824, at *12 (Fed. Cl. Spec. Mstr. June 12, 2015) (finding that "because Dr. Marks' opinion is based on a false assumption regarding the onset of J.R.B.'s condition, and the incorrect assumption of a 'stepwise regression' after each vaccine administration, it should not be credited"). Absent the opinions of Drs. Musio, Souayah, and Sanka, petitioner's medical records are not otherwise sufficient to support petitioner's burden of proof under *Althen* prong two, as confirmed in Dr. Sanka's affidavit. (Ex. 22.)

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). As previously explained, Dr. Souayah opined that CIDP can be causally related to either vaccinations or infections occurring up to six weeks earlier. (Ex. 26, p. 14.) This is also consistent with the time period for a Table Injury of GBS. 42 C.F.R. § 100.3(a)(XIV)(D). In some cases, special masters have even found that this period can be up to two months. *E.g. Barone v. Sec'y of Health & Human Servs.*, No.11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014). However, having concluded that onset of petitioner's neurologic symptoms occurred during his March 21, 2018 hospitalization, onset of what would be CIDP or GBS occurred more than 80 days post-vaccination. Accordingly, petitioner cannot meet his burden of proof under either *Althen* prong three or under the table requirements for GBS.[20]

[20] Additionally, as explained above, a diagnosis of CIDP is an exclusionary criterion for a Table Injury of GBS. 42 C.F.R. § 100.3(c)(15)(vi). In this case, Dr. Souayah opined that petitioner's condition was more likely to be CIDP rather than GBS because, based on his assessment of onset occurring in early January, the time from initial onset to nadir would be greater than eight weeks. (Ex. 26, p. 13.) The vaccine injury table likewise explains that GBS reaches its nadir after no more than 28 days. 42 C.F.R. § 100.3(c)(15)(i).

VII. Conclusion

There is no question that petitioner has suffered and that the events discussed throughout this decision have profoundly affected his life. He has my sympathy and I do not question his sincerity in bringing this claim. However, for all the reasons discussed above, I find that petitioner has not met his burden of proof in this case. Therefore, this case is dismissed.[21]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

Accordingly, acceptance of Dr. Souayah's assumption regarding onset would necessarily rule out any claim based on the table injury of GBS.

[21] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.